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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/697,923	10/29/2003	Christoph D. Karp	131-US	9644	
32763	7590 04/14/2005		EXAMINER		
	EAM, INC. MADRE VILLA AVE.		CYGAN, MICHAEL T		
	A, CA 91107-2928		ART UNIT	PAPER NUMBER	
			2855		
		DATE MAILED: 04/14/2005			

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application I	No.	Applicant(s)					
	10/697,923		KARP ET AL.	· (cm)				
Office Action Summary	Examiner		Art Unit	(8, 4				
	Michael Cyga	n	2855					
The MAILING DATE of this communication a Period for Reply	1		orrespondence add	ress				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status								
1) Responsive to communication(s) filed on 14	October 2004.							
2a)⊠ This action is FINAL. 2b)□ This action is non-final.								
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is								
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.								
Disposition of Claims								
4) Claim(s) <u>1,3 and 6-34</u> is/are pending in the	application.	•						
4a) Of the above claim(s) is/are withdrawn from consideration.								
5) Claim(s) is/are allowed.								
6)⊠ Claim(s) <u>1,3,6-31,33 and 34</u> is/are rejected.								
7)⊠ Claim(s) <u>32</u> is/are objected to. 8)□ Claim(s) are subject to restriction and/or election requirement.								
8) Claim(s) are subject to restriction and	i/or election requ	nement.						
Application Papers								
9) The specification is objected to by the Exami	ner.		•					
10)⊠ The drawing(s) filed on <u>29 <i>October 2003</i></u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
11) The oath or declaration is objected to by the	Examiner. Note	the attached Office	Action or form PTC	D-152.				
Priority under 35 U.S.C. § 119								
12)☐ Acknowledgment is made of a claim for forei	gn priority under	35 U.S.C. § 119(a)	-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:								
1. Certified copies of the priority documents have been received.								
2. Certified copies of the priority documents have been received in Application No								
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).								
* See the attached detailed Office action for a list of the certified copies not received.								
		•						
		•						
Attachment(s)								
1) Notice of References Cited (PTO-892)	4)	Interview Summary						
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date	,	Paper No(s)/Mail Da Notice of Informal P Other:		152)				
U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04) Office	Action Summary	Pa	rt of Paper No./Mail Dat	e 04122005				

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The applied reference U.S. 6,184,859 B2 has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

1. Claims 27-30 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ocvirk (Analyt. Meth. Instrumentation 1995) in view of Shimada (US 4,137,161) and Hu (U.S. 6,623,860 B2). Ocvirk teaches a microfluidic HPLC comprising a microfluid separation column having an optical detection region free of stationary phase material and bounded by a transmissive window; see Figure 1. The separation column is filled with packed particulate stationary phase material held by a frit; see page 78, left hand column. The microchip is substantially planar and formed from a plurality (two) or substantially planar device layers; see Figure 1. Ocvirk teaches operation at 10 bar, equaling 145 psi; see page 80, left hand column. Ocvirk teaches the claimed device except for a porous material disposed downstream of the optical detection region and acting to elevate the backpressure, and interpenetrably bound polymer layers holding multiple regions.

Shimada teaches a HPLC device having separation column, optical detection region, and a "flow passage resisting member" which may take the form of a monolithic packed column (a "tube packed with filler") disposed downstream of the optical detection region to elevate the pressure in the detector cell; see Figure 1 and column 2 line 41 through column 3 line 18. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a second column downstream of the detection region as taught by Shimada in the invention taught by Ocvirk to form a

backpressure column, since Shimada teaches that this allows analysis of solutions which tend to evolve gas; see column 3 lines 13-15.

Hu teaches a separation system having multiple separation channels formed from a plurality of stencil interpenetrably bound polymer layers; see columns 7-9. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple separation channels formed from a plurality of stencil interpenetrably bound polymer layers as taught by Hu in the invention taught by Ocvirk, to form the structure since Hu teaches that such a structure provides leak proof seals and performs multiple analyses.

 Claims 1, 3, 6-12, 21-23, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ocvirk (Analyt. Meth. Instrumentation 1995) in view of Shimada (US 4,137,161) and in view of Koehler (U.S. 6,814,859 B2).

Ocvirk teaches a microfluidic HPLC comprising a microfluid separation column having an optical detection region free of stationary phase material and bounded by a transmissive window; see Figure 1. The separation column is filled with packed particulate stationary phase material held by a frit; see page 78, left hand column. The microchip is substantially planar and formed from a plurality (two) or substantially planar device layers; see Figure 1. Ocvirk teaches operation at 10 bar, equaling 145 psi; see page 80, left hand column. Ocvirk teaches the claimed device except for a porous material

disposed downstream of the optical detection region and acting to elevate the backpressure, and interpenetrably bound polymer layers holding multiple regions.

Shimada teaches a HPLC device having separation column, optical detection region, and a "flow passage resisting member" which may take the form of a monolithic packed column (a "tube packed with filler") disposed downstream of the optical detection region to elevate the pressure in the detector cell; see Figure 1 and column 2 line 41 through column 3 line 18. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a second column downstream of the detection region as taught by Shimada in the invention taught by Ocvirk to form a backpressure column, since Shimada teaches that this allows analysis of solutions which tend to evolve gas; see column 3 lines 13-15.

Koehler teaches a porous membrane disposed in an adhesiveless, stencilled polymer substrate downstream of the separation column; see abstract; Figure 1C; column 3 lines 18-44; and columns 6-9. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a porous membrane disposed in an adhesiveless, stencilled polymer substrate downstream of the separation column as taught by Koehler in the invention taught by Ocvirk in view of Shimada to form the backpressure regulator, since Koehler teaches that this minimizes wicking and is readily bonded to microstructures.

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- 3. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ocvirk (Analyt. Meth. Instrumentation 1995) in view of Shimada (US 4,137,161) and in view of Koehler (U.S. 6,814,859 B2) as applied to claim 1, further in view of Soga (US 2003/0230524 A1). The claims are considered to be taught except for the layers comprising a fluidic distribution network including a plurality of columns leading to a plurality of detection regions each having light source and detector. Soga teaches a HPLC device having a fluidic distribution network comprising mobile phase supply, separation columns, optical detection regions each having light source and detector; see entire document, especially Figure 1, paragraphs 0007, 0010-0012, 0025, 0031-0035, and 0038-0044. It would have been obvious to use a fluidic distribution network comprising mobile phase supply, separation columns, optical detection regions each having light source and detector as taught by Soga in the invention taught by Ocvirk to form a sensing array, since Soga teaches the advantages of speed of processing, high reproducibility, low fluid resistance, and high separation performance; see paragraph 0007.
- 4. Claims 13-15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ocvirk (Analyt. Meth. Instrumentation 1995) in view of Shimada (US 4,137,161) as applied to claim 27, further in view of Soga (US 2003/0230524 A1). The claims are considered to be taught except for the

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layers comprising a fluidic distribution network including a plurality of columns leading to a plurality of detection regions each having light source and detector. Soga teaches a HPLC device having a fluidic distribution network comprising mobile phase supply, separation columns, optical detection regions each having light source and detector; see entire document, especially Figure 1, paragraphs 0007, 0010-0012, 0025, 0031-0035, and 0038-0044. It would have been obvious to use a fluidic distribution network comprising mobile phase supply, separation columns, optical detection regions each having light source and detector as taught by Soga in the invention taught by Ocvirk to form a sensing array, since Soga teaches the advantages of speed of processing, high reproducibility, low fluid resistance, and high separation performance; see paragraph 0007.

5. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ocvirk (Analyt. Meth. Instrumentation 1995) in view of Shimada (US 4,137,161) and in view of Soga (US 2003/0230524 A1) as applied to claim 13, further in view of Hu. The claimed invention is considered to be taught except for a plurality of adhesiveless polymer layers. Hu teaches a separation system having multiple separation channels formed from a plurality of stencil interpenetrably bound polymer layers; see columns 7-9. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple separation channels formed from a

plurality of stencil interpenetrably bound polymer layers as taught by Hu in the invention taught by Ocvirk, to form the structure since Hu teaches that such a structure provides leak proof seals and performs multiple analyses.

Response to Arguments

6. Applicant's arguments with respect to the claims have been considered but are most in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Cygan whose telephone number is (571) 272-2175. The examiner can normally be reached on 8:30-6 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Lefkowitz can be reached on 571-272-2180. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

